

REMARKS/ARGUMENTS

Claims 57, 59-64, 66-83, 87-89, 92-93, 97-104, 109-110, 113-169, and 176-189 are currently pending the present application. Claims 57, 59-64, 72, 75, 87-92, 104, 109-110, 113-115, and 157-158 were withdrawn by the Examiner in view of Election of Species and Restriction requirements.

Claims 66, 70, 93, 124 are amended.

Claims 84-86, 90-91, 94-96, 105-108, 111-112, and 170-175 have been canceled without prejudice or disclaimer of any subject matter. Claims 1-56, 58 and 65 were previously canceled.

Claims 176-189 are added.

Support for the amendments to claims 66, 70, 93, 124 can be found in the claims and throughout the specification, as originally filed.

Support for new claims 176-189 can be found in the claims and throughout the specification, as originally filed.

No new matter has been added.

Applicant wishes to thank the Examiner for withdrawing the election of species requirements regarding the hydrophilic, active agent, and lysolipid, and for withdrawing the restriction of the method claims of Group III. Reconsideration of the examined claims is requested in view of the remarks below.

Claim Rejections Under 35 U.S.C. § 112

Claims 124, 171-172, 174 and 175 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In view of the above amendment, Applicant submits that the rejections are rendered moot. In particular, claims 171-172, 174 and 175 have been canceled. Regarding claim 124, Applicant has removed the phrase “antitumor agent”, in view of the Examiner’s indication that the term “antitumor” falls within the scope of the term “antineoplasia.”

Accordingly, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Claim Rejections Under 35 U.S.C. § 102

Claims 66, 69-71, 73-74 and 77, 84-86, 93, 105-107, 116-122, 124-125, 128, 131-133, 136-144, 147-153, 159, 161-171 and 173 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ogawa (U.S. Patent No. 5,094,854).

Applicant submits that the rejection is rendered moot in view of the above amendments. In particular, independent claims 66, 70, and 93 have been amended to recite that the “one or more surface active agents” of the second component of a gel-phase lipid bilayer membrane are selected from the group consisting of “lysolipids, bile acids, glyceryl monooleate, ceramides, PEG-ceramides, and fatty acids.”

By contrast, as shown in column 2, lines 36-64 of Ogawa, the reference is limited to a liposomal membrane that merely includes the combination of selected phospholipids. In fact, as recited at column 3, lines 16-20, and as evidenced by the Examples of Ogawa, the combination of only DPPC and DSPC in a liposomal membrane is clearly “advantageous” and the object of that disclosure. As such, the claimed combination of first and second components in the gel-phase lipid bilayer membrane is clearly not described or suggested by the reference.

Accordingly, withdrawal of this rejection under 35 U.S.C. § 102(b) and the allowance of the present claims are requested.

Claims 66, 69, 77, 84-86, 93, 97, 105-107, 116-118, 121-122, 124-125, 128, 131-136 and 162-170 are rejected under 35 U.S.C. § 102(b) as being anticipated by Eibl (U.S. Patent No. 5,626,867).

In view of the above amendments, Applicant submits that the rejection is rendered moot. In particular, as shown and discussed above, Applicant has amended the independent claims to recite that the “one or more surface active agents” of the second component of a gel-phase lipid bilayer membrane are selected from the group consisting of “lysolipids, bile acids, glyceryl monooleate, ceramides, PEG-ceramides, and fatty acids.” (Amended claims 66, 70, and 93).

By contrast, Eibl merely describes a liposomal composition may include cholesterol, selective phospholipids, and phosphatidic acids. (See column 1, line 65 through column 2, line 44 of Eibl). The reference also indicates that a preferred composition includes cholesterol and

selected phospholipids. However, this combination clearly does not encompass the first and second component combination of the gel-phase lipid bilayer membrane of the claimed invention. (See column 3, lines 32-34). Therefore, Eibl does not describe or suggest the claimed invention.

Accordingly, withdrawal of this rejection under 35 U.S.C. § 102(b) and the allowance of the claims are requested.

Claim Rejections under 35 U.S.C. § 103

Claims 121-123, 125-127, 129-130, 152-156 are rejected under 35 U.S.C. § 103(a) as obvious over Ogawa.

Applicant submits that the present claims are not obvious in view of Ogawa. In particular, as discussed above, the independent claims have been amended to recite a component combination that is not described or suggested by Ogawa. As such, the dependent claims, which refer to the active agents, are also novel and non-obvious.

Accordingly, withdrawal of this rejection under 35 U.S.C. § 103(a) and the allowance of the claims are requested.

Claims 66-71, 73, 74, 76-86, 93, 97-103, 105-107, 116-136, 137-156 and 159-172 are rejected under 35 U.S.C. § 103(a) as obvious over Hristova (Micromolecules, vol. 28, pp. 7693-7699, 1995) in combination with Ogawa.

Applicant submits that the present claims are not obvious over Hristova, alone in combination with Ogawa, for reasons of record and those discussed below.

Applicant notes that Hristova describes several combinations of materials at page 7695 that may be included in liposome bilayers, including DPPC. However, as acknowledged by the Examiner, Hristova does not use hyperthermia and provides no description of drug delivery from a liposome. (See Present Office Action at page 5, paragraph 9).

Moreover, Hristova does not provide any description of a liposomal formulation containing DPPC and a lysolipid. To the contrary, the only apparent description of a lysolipid bilayer is at page 7697 ("Phospholipid:Lysolipid Bilayers"), in which the reference recites incorporating mixtures of POPE-PEG:EPC:MOPC. However, Applicant notes that the lysolipid

EPC (egg phosphatidylcholine) forms a liquid crystalline bilayer, not a gel-phase bilayer. As such, the reference's disclosure is entirely different from the description in Ogawa and completely out of the scope of the gel-phase bilayer of the present claims.

Moreover, it appears that the reference is only concerned with the specific development and incorporation of "PEG lipids" in "phospholipid bilayers". (See Abstract, Results, and Discussion sections of Hristova). By contrast, Ogawa, as discussed above, indicates that it is advantageous to merely include, among other components, DPPC and DSPC in a liposomal membrane. There is no such indication of PEG lipid incorporation, or description of the activity of a liposomal membrane at room temperature. As such, it clearly would not be obvious to rely on the disclosure of Ogawa to modify Hristova, or vice versa, since the references teach away from each other.

Accordingly, withdrawal of this rejection under 35 U.S.C. § 103(a) and the allowance of the claims are requested.

New Claims 176-189

Applicants submits that new claims 176-189 are novel and unobvious over the above cited references. In particular, Ogawa, Eibl, and Hristova do not describe or suggest the specific combination of components and mole percent ranges, as recited in independent claims 176 and 183. Accordingly, the allowance of claims 176-189 is respectfully requested.

Double Patenting Rejection

Claims 66-71, 73, 74, 76-86, 93, 97-103, 105-107, 116-136, 137-156 and 159-172 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-68 of U.S. Patent No. 6,726,925.

In view of the above amendments, Applicant requests that the Examiner hold the rejection in abeyance until there is an indication of allowable subject matter.

In view of the above amendments and remarks, Applicant believes the pending application is in condition for allowance. An expedited notification of allowance is kindly

requested. If, however, there are any issues that the Examiner would like to discuss, the Examiner is invited to contact Applicant's representative at the number listed below.

A one-month extension of time fee is due with this response. The Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any overpayment to Deposit Account No. 22-0185, under Order No. 14514-00007-US1 from which the undersigned is authorized to draw.

Dated: August 16, 2007

Respectfully submitted,

Electronic signature: /Bryant L. Young/
Bryant L. Young
Registration No.: 49,073
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 331-7111
(202) 293-6229 (Fax)
Attorney for Applicant

50039_1